Multistate utilization, processes, and outcomes of carotid endarterectomy

Timothy F. Kresowik, MD,[a,b] Dale Bratzler, DO, MPH,[c,d] Herbert R. Karp, MD,[e] Rebecca A. Hemann, BLS,[b] Marc E. Hendel, MS,[b] Sherry L. Grund, RN,[b] Marian Brenton, MPA, RN,[b] Edward F. Ellerbeck, MD, MPH,[f] and **David S. Nilasena, MD, MSPH,[g]** *Iowa City and West Des Moines, Iowa; Tulsa and Oklahoma City, Okla; Atlanta, Ga; Dallas, Tex; and Kansas City, Kan*

Objectives: **The purpose of this study was to describe variation in utilization, care processes, and outcomes for carotid endarterectomy (CEA) procedures in 10 states.**

Methods: **We reviewed the medical records of Medicare patients who underwent 10,561 CEA procedures between June 1, 1995, and May 31, 1996, in 10 different states to determine indications, care processes, and outcomes. This study also included medical record review of hospital readmissions within 30 days of the procedure and identification of out-of-hospital deaths from the Medicare beneficiary files.**

Results: **Utilization rates of CEA varied from 25.7 to 38.4 procedures per 10,000 Medicare beneficiaries among states. The overall combined event rate (30-day stroke or mortality) was 5.2% for primary CEA alone (n = 9945). The mortality rate was 1.5%, and the nonfatal stroke rate was 3.7%. Combined event rates (CEA alone) by surgical indication were 7.7% for stroke (n = 1037), 7.4% for transient ischemic attack (n = 1304), 5.3% for nonspecific symptoms (n = 3713), and 3.7% for asymptomatic patients (n = 3891). The combined event rates (CEA alone) among states ranged from 4.1% to 7.7% with the event rates in asymptomatic patients ranging from 2.3% to 6.7%. In a multivariate analysis (correcting for indication), the use of preoperative antiplatelet agents (odds ratio [OR], 0.70), intraoperative heparin (OR, 0.49), and patch angioplasty (OR, 0.73) was significantly associated with lower combined event rates. There were significant differences among states in the use of preoperative antiplatelet therapy (range, 56%-70%) and patch angioplasty (range, 11%-49%). Combined event rates for repeat procedures (n = 380) and CEA combined with coronary artery bypass grafting (n = 236) were 6.3% and 17.4%, respectively.**

Conclusions: **The striking variation among states suggests that there is room for improvement in the utilization, care processes, and outcomes of CEA. All surgeons performing CEA should participate in outcome assessment and adopt protocols that include the routine administration of antiplatelet agents preoperatively, the use of heparin intraoperatively, and patch angioplasty of the endarterectomy site. (J Vasc Surg 2001;33:227-35.)**

The efficacy of carotid endarterectomy (CEA) in stroke prevention for patients with symptomatic and asymptomatic carotid stenosis has been well established in randomized trials.[1-5] However, the therapeutic index is narrow, especially for patients who are asymptomatic. The randomized trials required each participating surgeon to have a proven track record of low morbidity/mortality for CEA.[6,7] The trials also limited entry to patients who were thought to be at low operative risk and for whom long-term survival was expected.[6,7] These limitations suggest that caution should be exercised in extrapolating the results of the randomized trials to all patients and surgeons.

The Health Care Financing Administration (HCFA) began the Health Care Quality Improvement Program (HCQIP) in 1992.[8] This new initiative changed the focus of the state-based, HCFA-funded, Peer Review Organizations from individual case review to performance of quality improvement projects by the use of larger data sets. Norman Hertzer, on behalf of the joint vascular societies, approached then HCFA administrator Bruce Vladek in 1994 regarding the need for HCFA to focus attention on the outcomes of vascular procedures in the Medicare population.[9] The initiation of the HCQIP and the effort of the vascular societies created the background that allowed the funding of a 10-state project to examine and attempt to improve the outcomes of CEA in the Medicare population. This report details the results of the baseline data collection from this project.

METHODS

A random sample of 10,561 CEA procedures (*International Classification of Diseases, Ninth Revision, Clinical Modification* [*ICD-9-CM*] procedure code of 38.12—endarterectomy of vessels of head and neck) per-

From the University of Iowa College of Medicine[a]; the Iowa Foundation for Medical Care[b]; Oklahoma State University College of Osteopathic Medicine[c]; the Oklahoma Foundation for Medical Quality, Inc[d]; the Georgia Medical Care Foundation[e]; the University of Kansas Medical Center[f]; and the Health Care Financing Administration.[g]

Competition of interest: nil.

The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsements by the US government. The author assumes full responsibility for the accuracy and completeness of the ideas presented.

Presented at the Joint Annual Meeting of the Society for Vascular Surgery and the American Association for Vascular Surgery, Toronto, Ontario, Canada, Jun 11, 2000.

Reprint requests: Timothy F. Kresowik, MD, Department of Surgery, UIHC, 200 Hawkins Drive, Iowa City, IA 52242-1086 (e-mail: timothy-kresowik@uiowa.edu).

24/6/111881
doi:10.1067/mva.2001.111881

formed on patients with discharge dates between June 1, 1995, and May 31, 1996, was identified with the Medicare Provider Analysis and Review (MEDPAR) Part A claims files from Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Michigan, Nebraska, Ohio, and Oklahoma. Patients eligible for Medicare include all patients 65 years and older, patients with total disability, and those who have chronic renal failure requiring dialysis. The cases identified for further analysis were from a universe of 28,083 CEA discharges during that time period in the 10 states. The sampling strategy was designed to obtain an adequate number of cases from each of the states, based on a power calculation with an estimated frequency of combined events (stroke or mortality) of 6% with a 95% CI and an error of ± 1.5%. A 50% oversampling of the calculated individual state samples except Iowa and Nebraska, which had 100% of cases selected because of ongoing CEA quality improvement projects, resulted in a sampling fraction that varied from 0.2 to 1.0 (Appendix I). The smallest individual state sample was 816 procedures, and the largest was 1314 procedures. The MEDPAR files were also used to identify any hospital admission that occurred for the beneficiaries in the CEA sample within 30 days of the discharge date of the primary admission. Records from any of these hospitalizations with any admitting or discharge diagnosis code suggesting a cerebrovascular accident (*ICD-9-CM* codes 430-438 [cerebrovascular disease]; 784.3 [aphasia]; 784.5 [dysphasia]; 342 [hemiplegia]; and 344 [paralysis]) were reviewed. The Medicare Enrollment Database was used to identify deaths that occurred within 30 days of the procedure to capture any deaths that occurred without an associated hospital admission.

Data collection. Requests for copies of the entire medical record for the primary admission and any readmissions were sent to the hospitals. Compliance with these requests is mandated by federal statute as part of participation in the Medicare program. The costs associated with copying and mailing medical records were reimbursed to the institution. A data collection tool was created for medical record abstraction by trained abstractors.

Each medical record was comprehensively reviewed to determine patient demographics, the indication for the procedure, perioperative care processes, and postoperative outcomes. The records were reviewed initially by trained abstractors at a HCFA Clinical Data Abstraction Center (DynKePRO, York, Pa). Data were abstracted from medical records directly into a computerized data entry system with an on-line edit check and data definitions to improve accuracy of data collection.

An extensive effort was made to validate the abstraction process with respect to identification and classification (major vs minor stroke) of adverse outcomes. The medical records of all patients identified as having postoperative strokes after the initial chart abstraction were independently rereviewed by two clinicians with expertise in stroke. A subset of patients classified by the chart abstractors as having no postoperative stroke were subjected to the same clinician validation process to determine if any postoperative strokes were missed during chart abstraction. This sensitivity validation subset (n = 356) was chosen on the basis of administrative characteristics (hospital length of stay > 5 days, discharge codes suggesting postoperative neurologic complications, and discharges other than to home) that had been shown to be associated with postoperative strokes. The results presented reflect the validated data.

Definitions. Indications for CEA were classified into four mutually exclusive categories. Patients were considered to have *stroke* as the indication for the procedure only if they had documented ipsilateral hemispheric symptoms that persisted for more than 24 hours within 90 days before the procedure. Similarly, patients were considered to have *transient ischemic attack (TIA)* as the indication only if transient (< 24 hours) ipsilateral hemispheric symptoms occurred within 90 days before the procedure. Patients were considered to be *asymptomatic* only if there was no history at any time before the procedure of cerebrovascular symptoms or events in either the anterior or posterior circulations. All other patients (eg, those with remote ipsilateral symptoms, global or vertebrobasilar symptoms, contralateral hemispheric symptoms) were classified in a *nonspecific* category. These definitions were used to create relatively clean stroke, TIA, and asymptomatic indication groups with high reproducibility, given the limitations of retrospective medical record review.

CEA procedures were classified into three procedure groups. *CEA with coronary artery bypass grafting (CABG)* included patients who had both a CEA and CABG during the same operative episode. *CEA reoperation* was used for patients who had a prior ipsilateral CEA. All other patients were included in a *CEA-alone* group. *Preoperative antiplatelet therapy* was defined as aspirin or ticlopidine that was given to the patient within 2 days before or on the day of the procedure (but before the procedure).

For the purpose of outcome classification, a *postoperative stroke* was considered to have occurred if any new or worsening central nervous system deficit developed during the postoperative period and persisted for more than 24 hours. Postoperative strokes were classified as major or minor by looking at a point in time 5 days after the stroke or at hospital discharge, whichever occurred sooner. If the patient had a new persistent deficit that resulted in a need for assistance with ambulation or eating or had significant difficulty with speaking, the patient was considered to have had a *major stroke*. Patients without disability at 5 days after the event were considered to have had a *minor stroke*. These relatively simple definitions allowed for reproducible classification by abstractors using information typically available in the medical record. Deaths were considered *stroke related* if the death was associated with a major stroke. If there was no evidence of major stroke associated with the death, the death was classified as *nonstroke related*.

Data analysis. We examined simple descriptive statistics for the processes and outcomes of CEA care. We

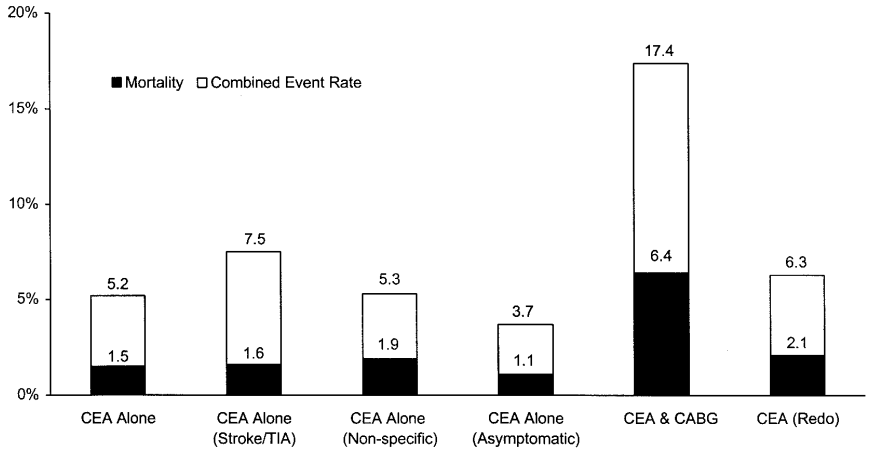

Fig 1. Combined event rates (30-day stroke or mortality) and mortality rates for 10-state aggregate for each procedure category (CEA alone [n = 9945), CEA/CABG [n = 236], and CEA redo [n = 380]) and CEA-alone indication subsets (TIA/stroke [n = 2341], nonspecific [n = 3713] and asymptomatic [n = 3891]). *CABG,* Coronary artery bypass grafting; *CEA,* carotid endarterectomy; *TIA,* transient ischemic attack.

tested for the significance of the difference between each state and the aggregate rates in processes with PROC LOGISTIC and PROC CATMOD (Version 6.12; SAS Institute, Cary, NC).

To examine the relative impact of different processes of care on CEA outcomes in the CEA-alone subgroup, we first evaluated each process as an independent variable. Each process was examined by means of a multivariate logistic regression model with the combined event rate as the dependent variable to account for the effect of indication. The independent variables in each model were dichotomous variables representing the process and each indication. PROC LOGISTIC (Version 6.12; SAS Institute) was used to compute the Wald statistics. A similar analysis was performed to compare each state's rates for outcomes (ie, stroke or mortality rate) with the aggregate rate. In this analysis, the process variable was replaced with a dichotomous variable indicating the state.

The counts of the Medicare population for each of the 10 states were obtained from the HCFA Web site (http://www.hcfa.gov/stats/histenr.htm). The number of CEA procedures per 10,000 Medicare beneficiaries by indication was extrapolated from those counts, the CEA universe in the state, the sampling fraction, and the observed indication fraction in each state sample. Statistically significant variation from the aggregate was determined with the Mantel-Haenszel χ^2 test with one degree of freedom (Centers for Disease Control and Prevention's Epi Info, Version 6).

The variation in indication type and process utilization was analyzed through several univariate models with the indication or process as the dependent variable and a categoric variable with a different value for each state as the independent variable. PROC CATMOD (Version 6.12; SAS Institute) was used to analyze the models.

RESULTS

The number and type of procedures in the state samples as well as patient age, sex, and indication for the procedure are provided in Appendix II. The 10,561 procedures in the 10-state sample were performed in 10,030 patients. The patients' ages ranged from 39 to 95 years; 4.9% of patients were younger than 65 and 19% were 80 and older. The median length of stay (including day of discharge) was 4 days with the median postoperative length of stay of 2 days.

Care process information for the statewide samples for the CEA-alone procedures is presented in Appendix III. Preoperative arteriograms were documented in 72%. Preoperative aspirin or ticlopidine administration was documented in 62%. Heparin was administered intraoperatively in 98.6% of procedures and was reversed in 55%. The procedure was performed with patients under local or regional anesthesia in 10% of cases, and routine shunting (no monitoring documented) was used in 50%. The procedure was performed without cerebral monitoring and without shunting in 19%. Patch angioplasty was used in 29% of cases with 74% of the patches being prosthetic. Some form of intraoperative, postendarterectomy assessment of the operative site with B-mode ultrasound imaging/duplex, continuous wave Doppler scan, or angiography was documented in 29% of cases.

Aggregate outcome data by procedural category are displayed in Fig 1. Detailed procedural outcome data including stratification by state and indication category are available in Appendix IV. The 30-day combined event (stroke or mortality) rate for the CEA-alone patients in the 10-state sample was 5.2%. The mortality rate was 1.5%, and the nonfatal stroke rate was 3.7%. The combined event rate was 7.7% in patients with prior stroke, 7.4% in patients with preexisting TIAs, 5.3% in patients with nonspecific symptoms, and 3.7% in asymptomatic patients. Combined event

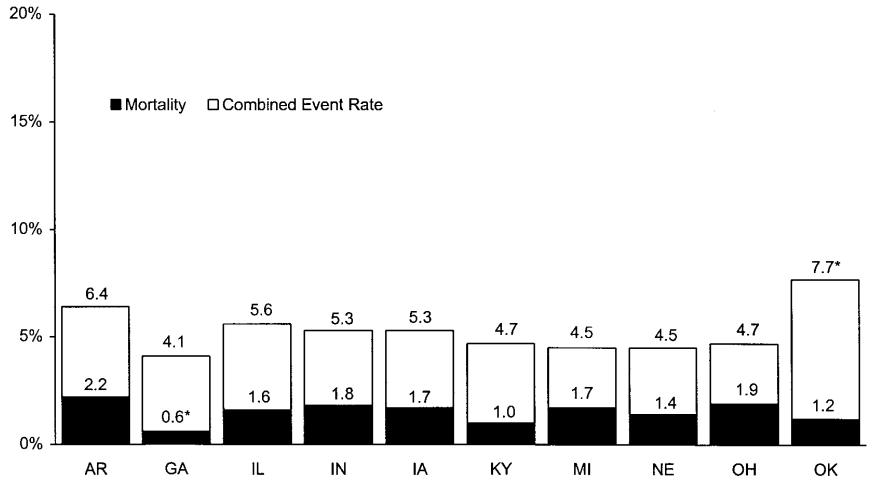

Fig 2. Combined event rates (30-day stroke or mortality) and mortality rates for CEA-alone procedures (all indications) by state (Arkansas [n = 770], Georgia [n = 958], Illinois [n = 1064], Indiana [n = 1026], Iowa [n = 1265], Kentucky [n = 892], Michigan [n = 1141], Nebraska [n = 865], Ohio [n = 1143], and Oklahoma [n = 821]). *Asterisk* indicates significantly different from mean $P < .05$.

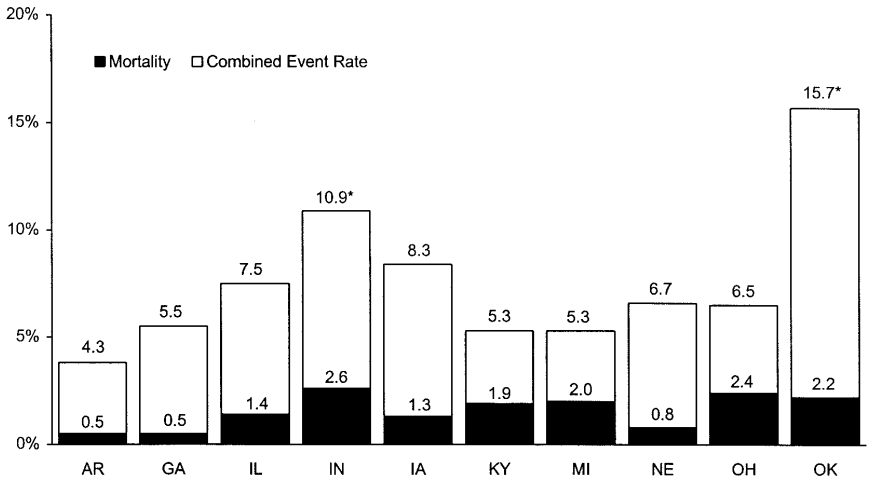

Fig 3. Combined event rates (30-day stroke or mortality) and mortality rates for CEA-alone procedures (TIA/stroke indication only) by state (Arkansas [n = 184], Georgia [n = 218], Illinois [n = 279], Indiana [n = 230], Iowa [n = 312], Kentucky [n = 207], Michigan [n = 247], Nebraska [n = 240], Ohio [n = 246], and Oklahoma [n = 178]). *Asterisk* indicates significantly different from mean $P < .05$.

rates varied significantly ($P < .005$), stratified by indication except for stroke versus TIA. Other complications included postoperative hemorrhage requiring a return to the operating room in 1.8%, cranial nerve injury in 2.0%, and hyperperfusion syndrome in 0.1%.

The 10-state, 30-day, combined event rate for the patients undergoing CEA/CABG was 17.4% ($P < .001$ vs CEA alone) with a mortality rate of 6.4% and a nonfatal stroke rate of 11.0%. Stroke and TIA were the indications for operation in only 12% of the patients undergoing CEA and CABG, and 55% were completely asymptomatic. The stroke/mortality rate in those patients undergoing CEA reoperation was 6.3% (P = not significant vs CEA alone), with the mortality rate being 2.1% and the nonfatal stroke rate, 4.2%.

There was significant variation in CEA utilization, indications, care processes, and outcomes among states. The number of CEAs performed in a state expressed per 10,000 Medicare beneficiaries ranged from a low of 25.7 in Illinois to a high of 38.4 in Michigan (Appendix I). The proportion of the procedures performed on asymptomatic patients ranged from 35% to 45% (Appendix II). The overall combined event rate varied from 4.1% to 7.7% among states (Fig 2). The individual state combined event rate in patients with ipsilateral hemispheric symptoms (stroke or TIA) ranged from a low of 4.3% to a high of 15.7% (Fig 3). The combined event rate in asymptomatic patients varied from 2.3% to 6.7% (Fig 4). Process variation among states (Appendix III) included preoperative antiplatelet use (56%-70%), heparin reversal (40%-68%), routine

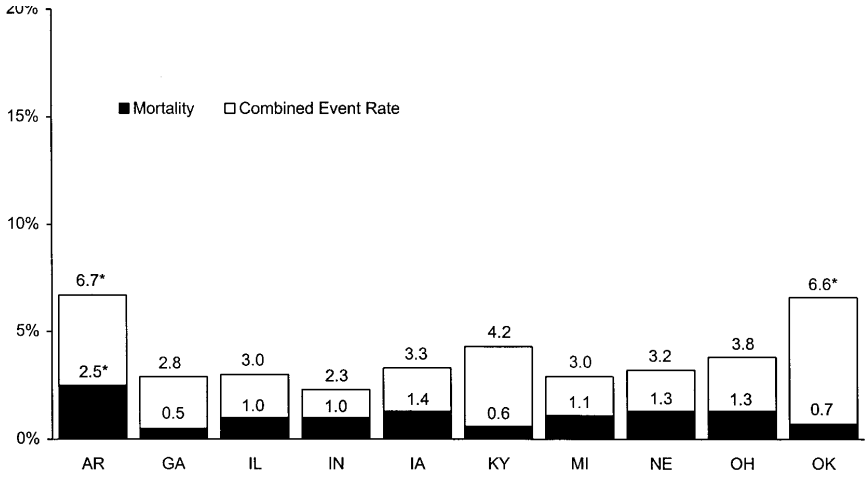

Fig 4. Combined event rates (30-day stroke or mortality) and mortality rates for CEA-alone procedures (asymptomatic indication only) by state (Arkansas [n = 284], Georgia [n = 422], Illinois [n = 406], Indiana [n = 394], Iowa [n = 512], Kentucky [n = 356], Michigan [n = 438], Nebraska [n = 317], Ohio [n = 473], Oklahoma [n = 289]). *Asterisk* indicates significantly different from mean $P < .05$.

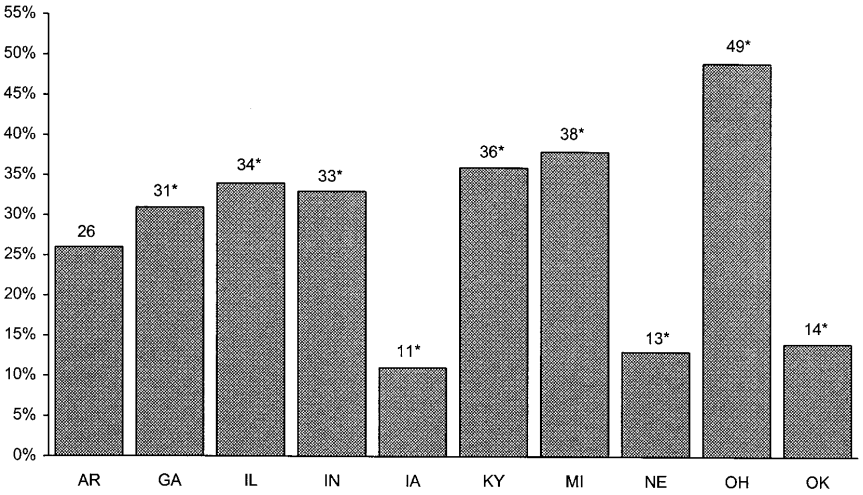

Fig 5. Use of patch angioplasty for CEA-alone procedures (all indications) by state. *Asterisk* indicates significantly different from mean $P < .05$.

shunting (23%-68%), no shunt and absent cerebral perfusion monitoring (10%-28%), and patching (11%-49%) (Fig 5). Also, in an analysis (correcting for indication) of the multistate CEA alone sample, the preoperative administration of aspirin or ticlopidine (30% risk reduction), the intraoperative use of heparin (51% risk reduction), and patching (27% risk reduction) were all associated with significantly lower combined event rates (Table).

DISCUSSION

The number of procedures in our study is more than five times larger than any previously reported community-wide, medical record review of CEA procedures (individual reports summarized in Appendix V).[10-21] Medical record review is necessary to determine the indication for the procedure, to determine care processes associated with the procedure, and to accurately capture complications. The Medicare databases also allowed us to identify hospital readmissions (regardless of whether the readmission occurred at the same hospital as the procedure) and out-of-hospital deaths. The only events missed in calculating 30-day event rates would be nonfatal neurologic events occurring after discharge from the procedural admission that did not result in another hospital admission.

Administrative databases (individual reports are summarized in Appendix VI) avoid the resource intensive process of medical record review and can contain attractively large numbers, but uniformly lack accurate information about indication for the procedure and postoperative complications other than death.[22-33] Given the observed variation in indication for CEA and the significant differences in outcome based on indication, we do not think

Process/outcome relationship (CEA alone—corrected for indication)

Predictor of stroke or mortality	P *value*	*OR*	*95% CI on OR*
Preoperative angiography	.06	1.22	0.99-1.51
Preoperative aspirin/ticlopidine*	.0001	0.70	0.59-0.84
Local/regional anesthesia	.4	0.88	0.65-1.20
Use of heparin*	.01	0.49	0.28-0.87
Reversal of heparin	.3	0.91	0.76-1.10
Use of patch*	.003	0.73	0.59-0.90
Use of vein patch	.8	1.03	0.74-1.44
Use of prosthetic patch*	.001	0.67	0.52-0.85
Use of EEG	.4	1.10	0.87-1.38
Monitoring of back pressure	.7	0.93	0.63-1.37
Shunt, no monitoring	.09	0.86	0.72-1.03
No monitoring, no shunt	.09	1.20	0.97-1.49
Postreconstruction assessment	.9	1.02	0.84-1.24

*Statistically significant predictor of stroke or mortality at P level < .05, while controlling for indication.
CEA, Carotid endarterectomy; *EEG*, electroencephalogram; *OR*, odds ratio.

that administrative data can be used for valid outcome comparisons. Administrative databases are also devoid of process information. Prospective registries (individual reports summarized in Appendix VII) have also been used to document the community-wide outcomes for CEA.[21,34-39] However, registries usually represent the results of selected providers (eg, vascular societies, volunteers) and often do not represent the community as a whole. Both administrative databases and registries are subject to reporting bias.

Common definitions of indication and outcomes are important if comparisons are to be made between studies. We chose our definitions of TIA, stroke, and asymptomatic so that comparisons could be made to the benchmarks achieved in the randomized trials. Our definition of asymptomatic is somewhat stricter than that used in the Asymptomatic Carotid Atherosclerosis Study (ACAS), in that we included patients in the asymptomatic category only if there was no prior history of events in any cerebral distribution (including the contralateral hemisphere). The value of stratifying patients (eg, those with remote ipsilateral hemispheric symptoms, contralateral symptoms, vertebrobasilar or global ischemia) not meeting the strict symptomatic or asymptomatic definition in a nonspecific category was confirmed by the intermediate combined event rate observed in this group of patients (TIA/stroke indication, 7.5%; nonspecific symptoms, 5.3%; asymptomatic, 3.7%).

It is encouraging that the overall Medicare patient stroke or mortality rate of 7.5% for symptomatic patients observed in the 10-state sample was only slightly higher than the 6.5% rate reported in the North American Symptomatic Carotid Endarterectomy Trial (NASCET) study (combined reports).[40] The higher morbidity/mortality rate could easily be explained by the older age of the population in this report (19% ≥ 80 years), compared with the NASCET population that excluded patients older than 79. The retrospective medical record review method used in this study, however, would not be as sensitive in identifying all neurologic events as would the prospective, mandatory, postoperative neurologic examinations performed as part of the NASCET.

The overall observed rate of combined events for asymptomatic patients (3.7%) is more troublesome given the 1.5% rate (excluding strokes included in the intention to treat analysis that occurred preoperatively) observed in the ACAS and the narrow therapeutic benefit of surgical versus medical therapy for asymptomatic patients.[41] It would be inappropriate to justify the higher rate in the older Medicare population, because selecting patients with low operative risk and longer expected survival is essential in identifying asymptomatic patients likely to benefit from CEA.

The relatively high stroke or mortality rate (17.4%) observed in the patients who underwent combined CEA/CABG indicates that caution should be exercised in recommending the combined approach. The observed stroke/mortality rate for CEA/CABG is especially disconcerting given the fact that more than half of the patients had no prior neurologic symptoms or events. The observed rate in the current study is higher than the rates identified in many single-institution reports.[42] In contrast, the overall combined event rate of 6.3% in patients undergoing repeat procedures was not significantly different from the event rate in patients undergoing primary (CEA-alone) procedures.

The most cogent observation in this study indicating a need for quality improvement is the striking variation in utilization, process, and outcomes among the states. Variation in the utilization of CEA has been described previously.[43,44] This is the first large scale report documenting the regional variation stratified by indication for the procedure. It is not surprising that most of the variation occurred in patients who were asymptomatic or had nonspecific symptoms. The 50% higher CEA utilization rate in Michigan versus Illinois is hard to explain or justify. To put this in perspective, if the Michigan utilization rate was applied to Illinois, more than 2000 additional Medicare patients would have undergone CEA in Illinois during the 1-year study period. Significant

variation also occurred in all of the care processes examined and likely reflects uncertainty about the utility of some of the processes. The rate of patching in Ohio (49%) was more than four times higher than the patching rate in Iowa (11%).

The observed variation in outcomes makes the strongest case for the need for quality improvement. The stroke or mortality rates in asymptomatic patients observed in Arkansas (6.7%) and Oklahoma (6.6%) were almost three times higher than the rate in Indiana (2.3%). If the observed rates in Arkansas and Oklahoma had been the surgical combined event rate in the ACAS, the trial certainly would not have indicated surgical benefit. If we extrapolate the observed indication and outcome results from this 10-state study to the entire US Medicare population and compare that prediction with an extrapolation using benchmark outcomes (NASCET, ACAS, best state observed rate in this study for nonspecific), more than 500 fewer deaths and 1000 fewer nonfatal strokes after CEA would have occurred in 1996.

The relationships observed between certain processes and outcomes are an equally important finding in this study. The significant risk reduction associated with preoperative antiplatelet drug administration and patching confirms the findings of small randomized trials indicating the benefit of these modalities.[45-48] Our results did not suggest an advantage of the use of vein over prosthetic patch material. We can extrapolate using the observed odds ratios for the three processes that we found were associated with better outcomes to predict hypothetical outcomes if the three processes had been used in all procedures. Eighteen percent of the procedures in our sample were associated with preoperative antiplatelet therapy, intraoperative heparin, and patching. The combined stroke or mortality rate for these procedures was 3.5%. We created a logistic regression model (controlling for indication) with the assumption that all surgeons used all three processes. On the basis of this model, we would predict 2800 fewer strokes or deaths after CEA in the US Medicare population in 1996 than would be predicted by extrapolating with the observed outcomes in this study. Caution must always be observed in using associations from a retrospective, observational study such as in the current study when establishing a clear cause and effect relationship. However, it seems likely that any bias introduced in an uncontrolled study would be that preoperative antiplatelet therapy and patching would be associated with procedures with predicted poorer outcomes. Symptomatic patients would seem more likely to be receiving antiplatelet agents preoperatively, and surgeons are more likely to patch a problematic endarterectomy site. Therefore, we think that the findings in this study and the cited randomized trial evidence justify a solid recommendation for universal administration of preoperative antiplatelet therapy and patching of the endarterectomy site.

CONCLUSIONS

Valid CEA outcome comparisons require stratification by indication for the procedure and the use of common definitions for indication and adverse outcomes. We suggest that three indication strata (TIA/stroke, asymptomatic, nonspecific) with definitions similar to those used in this study become the standard for future CEA outcome reporting. We found that the community-wide CEA outcomes for symptomatic Medicare patients were similar to those achieved in the NASCET. However, the combined event rates for asymptomatic patients were more than two times those observed in the ACAS. The combined event rates in patients undergoing CEA/CABG were unacceptably high. There was a striking variation in the utilization, care processes, and outcomes of CEA among the 10 states in this study, which indicates the potential and the need for quality improvement. We think that all surgeons performing CEA should participate in standardized outcome assessment and adopt protocols that include the routine administration of antiplatelet therapy before the procedure, the use of heparin intraoperatively, and closure of the endarterectomy site with a patch.

The analyses on which this publication is based were performed under contracts, entitled "Utilization and Quality Control Peer Review Organization," sponsored by the Health Care Financing Administration, Department of Health and Human Services. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore, required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcome.

REFERENCES

1. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Engl J Med 1991;325:445-53.
2. Mayberg MR, Wilson SE, Yatsu F, et al, for the Veterans Affairs Cooperative Studies Program 309 Trialist Group. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. JAMA 1991;266:3289-94.
3. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. JAMA 1995;273:1421-8.
4. European Carotid Surgery Trialists' Collaborative Group. Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST). Lancet 1998;351:1379-87.
5. Barnett HJM, Taylor DW, Eliasziw M, et al. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. N Engl J Med 1998;339:1415-25.
6. North American Symptomatic Carotid Endarterectomy Trial. Methods, patient characteristics, and progress. Stroke 1991;22: 711-20.
7. The Asymptomatic Carotid Atherosclerosis Study Group. Study design for randomized prospective trial of carotid endarterectomy for asymptomatic atherosclerosis. Stroke 1989;20:844-9.
8. Jencks SF, Wilensky GR. The health care quality improvement initiative. JAMA 1992;268:900-3.
9. Hertzer,NR. Presidential address: outcome assessment in vascular surgery—results mean everything. J Vasc Surg 1995;21:6-15.
10. Easton JD, Sherman DG. Stroke and mortality rate in carotid endarterectomy: 228 consecutive operations. Stroke 1977;8:565-8.
11. Brott TG, Thalinger K. The practice of carotid endarterectomy in a large metropolitan area. Stroke 1984;15:950-5.

12. Kempczinski RF, Brott TG, Labutta RJ. The influence of surgical specialty and caseload on the results of carotid endarterectomy. J Vasc Surg 1986;3:911-6.
13. Winslow CM, Solomon DM, Chassin MR, et al. The appropriateness of carotid endarterectomy. N Engl J Med 1988;318:721-7.
14. Richardson JD, Main KA. Carotid endarterectomy in the elderly population: a statewide experience. J Vasc Surg 1989;9:65-73.
15. McCrory DC, Goldstein LB, Samsa GP, et al. Predicting complications of carotid endarterectomy. Stroke 1993;24:1285-91.
16. Bratzler DW, Oehlert WH, Murray CK, et al. Carotid endarterectomy in Oklahoma Medicare beneficiaries: patient characteristics and outcomes. J Okla State Med Assoc 1996;89:423-9.
17. Karp HR, Flanders WD, Shipp CC, et al. Carotid endarterectomy among Medicare beneficiaries: a statewide evaluation of appropriateness and outcome. Stroke 1998;29:46-52.
18. Cebul RD, Snow RJ, Pine R, et al. Indications, outcomes, and provider volumes for carotid endarterectomy. JAMA 1998;279:1282-7.
19. Hallett JW Jr, Pietropaoli JA Jr, Ilstrup DM, et al. Comparison of North American Symptomatic Carotid Endarterectomy Trial and population-based outcomes for carotid endarterectomy. J Vasc Surg 1998;27:845-51.
20. Kucey DS, Bowyer B, Iron K, et al. Determinants of outcome after carotid endarterectomy. J Vasc Surg 1998;28:1051-8.
21. Kresowik TF, Hemann RA, Grund SL, et al. Improving the outcomes of carotid endarterectomy: results of a statewide quality improvement project. J Vasc Surg 2000:31;918-26.
22. Fisher ES, Malenka DJ, Solomon NA, et al. Risk of carotid endarterectomy in the elderly. Am J Public Health 1989;79:1617-20.
23. Edwards WH, Morris JA Jr, Jenkins JM, et al. Evaluating quality, cost-effective health care: vascular database predicated on hospital discharge abstracts. Ann Surg 1991;213:433-9.
24. Hsia DC, Krushat WM, Moscoe LM. Epidemiology of carotid endarterectomies among Medicare beneficiaries. J Vasc Surg 1992;16:201-8.
25. Segal HE, Rummel L, Wu B. The utility of PRO data on surgical volume: the example of carotid endarterectomy. QRB Qual Rev Bull 1993;19:152-7.
26. Ruby ST, Robinson D, Lynch JT, et al. Outcome analysis of carotid endarterectomy in Connecticut: the impact of volume and specialty. Ann Vasc Surg 1996;10:22-6.
27. Stukenborg GJ. Comparison of carotid endarterectomy outcomes from randomized controlled trials and Medicare administrative databases. Arch Neurol 1997;54:826-32.
28. Maxwell JG, Rutledge R, Covington DL, et al. A statewide, hospital-based analysis of frequency and outcomes in carotid endarterectomy. Am J Surg 1997;174:655-60.
29. Holloway RG Jr, Witter DM Jr, Mushlin AI, et al. Carotid endarterectomy trends in the patterns and outcomes of care at academic medical centers, 1990 through 1995. Arch Neurol 1998;55:25-32.
30. Perler BA, Dardik A, Burleyson GP, et al. Influence of age and hospital volume on the results of carotid endarterectomy: a statewide analysis of 9918 cases. J Vasc Surg 1998;27:25-33.
31. Hsia DC, Moscoe LM, Krushat WM. Epidemiology of carotid endarterectomy among Medicare beneficiaries: 1985-1996 update. Stroke 1998;29:346-50.
32. Wennberg DE, Lucas FL, Birkmeyer JD, et al. Variation in carotid endarterectomy mortality in the Medicare population. JAMA 1998;279:1278-81.
33. Morasch MD, Parker MA, Feinglass J, et al. Carotid endarterectomy: characterization of recent increases in procedure rates. J Vasc Surg 2000;31:901-9.
34. Hertzer NR, Avellone JC, Farrell CJ, et al. The risk of vascular surgery in a metropolitan community: with observations on surgeon experience and hospital size. J Vasc Surg 1984;1:13-21.
35. Rubin JR, Pitluk HC, King TA, et al. Carotid endarterectomy in a metropolitan community: the early results after 8,535 operations. J Vasc Surg 1988;7:256-60.
36. Hertzer NR, O'Hara PJ, Mascha EJ, et al. Early outcome assessment for 2228 consecutive carotid endarterectomy procedures: the Cleveland Clinic experience from 1989 to 1995. J Vasc Surg 1997;26:1-10.
37. Yates GN, Bergamini TM, George SM Jr, et al. Carotid endarterectomy results from a state vascular society. Kentucky Vascular Surgery Society Study Group. Am J Surg 1997;173:342-4.
38. Kantonen I, Lepantalo M, Salenius JP, et al. Influence of surgical experience on the results of carotid surgery. The Finnvasc Study Group. Eur J Vasc Endovasc Surg 1998;15:155-60.
39. Mayo SW, Eldrup-Jorgensen J, Lucas FL, et al. Carotid endarterectomy after NASCET and ACAS: a statewide study. J Vasc Surg 1998;27:1017-22.
40. Ferguson GG, Eliasziw M, Barr HW, et al. The North American Symptomatic Carotid Endarterectomy Trial: surgical results in 1415 patients. Stroke 1999;30:1751-8.
41. Moore WS, Young B, Baker WH, et al. Surgical results: a justification of the surgeon selection process for the ACAS trial. J Vasc Surg 1996;23:323-8.
42. Ricotta JJ, Faggioli G. Management of concomitant coronary bypass and carotid reconstruction. In: Loftus CM, Kresowik TF, editors. Carotid artery surgery. 1st Edition. New York: Thieme Medical Publishers, Inc; 2000. p. 137-46.
43. Tu JV, Hannan EL, Anderson GM, et al. The fall and rise of carotid endarterectomy in the United States and Canada. N Engl J Med 1998;339:1441-7.
44. Birkmeyer JD, Sharp SM, Finalyson SR, et al. Variation profiles of common surgical procedures. Surgery 1998;124:917-23.
45. Kretschmer G, Pratschner T, Prager M, et al. Antiplatelet treatment prolongs survival after carotid bifurcation endarterectomy: analysis of the clinical series followed by a controlled trial. Ann Surg 1990;211:317-22.
46. Lindlblad B, Persson NH, Takolander R, et al. Does low-dose acetylsalicylic acid prevent stroke after carotid surgery? A double-blind, placebo-controlled randomized trial. Stroke 1993;24:1125-8.
47. Abu Rahma AF, Khan JH, Robinson PA, et al. Prospective randomized trial of carotid endarterectomy with primary closure and patch angioplasty with saphenous vein, jugular vein, and polytetrafluoroethylene: perioperative (30-day) results. J Vasc Surg 1996;24:998-1006; discussion 1006-7.
48. Jackson MR, Clagett GP. Use of vein or synthetic patches in carotid endarterectomy. In: Loftus CM, Kresowik TF, editors. Carotid artery surgery. 1st Ed. New York: Thieme Medical Publishers, Inc; 2000. p. 281.

Submitted Jun 12, 2000; accepted Sep 7, 2000.

Please note that Appendices I through VII are available on the *Journal of Vascular Surgery* Web site (www.mosby.com/jvs).

DISCUSSION

Dr Norman R. Hertzer (Cleveland, Ohio). Dr Kresowik and all of the people working with him on this project have brought us, and the nation, probably the most refined Medicare dataset for carotid endarterectomy that has ever been reported. Unlike most Medicare surveys that are limited to an analysis of crude postoperative mortality rates, this one enlisted Peer Review Organizations to collect very specific information concerning preoperative indications, intraoperative management, and 30-day outcomes on the basis of an individual audit of over 10,000 patients in 10 states.

It is a remarkable study not only because it clearly tells us how successful we have been with carotid endarterectomy, but more important because it shows us with big, significant numbers how we can make it an even safer operation in the future. Should patients receive preoperative antiplatelet therapy? Yes, they should, because it reduces the stroke and/or mortality rate by 30%. Is carotid patching really necessary? Well, apparently so, because it also reduces the combined complication rate by 27%. Must the results of carotid endarterectomy be audited in every hospital? Absolutely, because if the utilization and risk can be three times higher in one state than in another, you can imagine the differences that exist between one hospital and another, especially if you consider all of the variables associated with low and high volumes.

I have one question for Dr Kresowik that should be of interest to the audience here and eventually in the *Journal of Vascular Surgery*. It was my understanding when this project was implemented in 1995 that the retrospective chart review would be used to establish baseline parameters and then would be followed by 3 years of prospective outcome assessment to determine whether the knowledge generated by the chart review, or perhaps just the surveillance itself, might somehow improve results. The problem that we encountered in Ohio is that, while the state PRO can invite hospitals to participate in prospective assessment, it cannot force them to participate even if it seems to be in the public interest for them to do so. In this regard, what has happened with Phase II of this project and will it be conducted at all?

Finally, I just want to remind you that HCFA initiated this project largely at the suggestion of these two societies. Therefore, I think all of us should be proud of this study and the job that Dr Kresowik and his team have done with it.

Dr Timothy F. Kresowik. Thanks very much, Norm. I think we also owe a personal debt of gratitude to Dr Hertzer, who went to HCFA on our behalf to encourage these kinds of outcome studies. I think his efforts did us all a favor in terms of having HCFA personnel see vascular surgeons as interested in something more than just how much we are paid. I don't mean to diminish at all the importance of our continued work to get our undervalued services properly reimbursed.

To answer your question, we do have an ongoing project. We have a similar sample of approximately the same number of patients with data collection underway now. The remeasurement period includes medical records from June 1998 to May 1999. There have been efforts in a number of the states to improve their outcomes. We presented our results from Iowa last fall at the Midwest Vascular meeting, and they were published in the May *Journal of Vascular Surgery*. In that report we found a decrease in the stroke mortality rate in 14 hospitals, from 6.5% in 1994 to 1.8% in 1998. Those 14 hospitals perform about 75% of the CEAs done in our state. I hope to find similar results in some of the other states when we do the remeasurement.

Dr David C. Brewster (Boston, Mass). I, too, would congratulate Dr Kresowik and his colleagues. I think this is a very important study and really illustrates the potential power of such careful outcome analysis to influence and hopefully improve practice.

Did your data, Tim, have any findings relative to several other important procedural variables, such as whether regional block or general anesthesia was used, whether or not EEG monitoring was employed, or if shunting was utilized? Did any of these variables correlate with outcome in any way?

Dr Kresowik. Thanks, David. As a person who does the procedure under regional anesthesia, I would have loved to have been able to stand up here and tell you that regional anesthesia was associated with better outcomes, but that was not the case. We did look at all those processes. For example, almost 20% of the cases received no monitoring and no shunt, and we did not find significantly poorer outcomes in that subgroup. There was a trend, but not a significant association. There were only three processes (heparin use, antiplatelet therapy, and patching) that were associated with significant risk reductions.

Dr Jack L. Cronenwett (Lebanon, NH). I am very excited about these data, which are extraordinarily powerful.

My question relates to whether you had an opportunity to correlate these outcomes with volume, either by hospital or by surgeon. Several studies have shown that volume outcome is particularly important in carotid surgery, and I wonder if that explains in part some of the variation that you observed?

Dr Kresowik. It's a very important question. When we started this project, we wanted to focus on quality improvement, and some of those kind of issues become very political. This project is based on review of the inpatient records, and one of the issues is that it can be very difficult to determine who was the operating surgeon. We have to cross-reference to physician claims. The surgical bill, as you know, is under Part B of Medicare, and this is a very large dataset. We are going to link all these patients to the surgeon that billed for the procedure, and then we can do the kind of analysis you requested. We also hope not only to link volume to outcome, but also to examine the impact of training. We can use the American Board of Surgery database and at least use board certification in a certain area, whether it be vascular, general surgery, cardiothoracic, or neurosurgery, as a surrogate for training. So we do want to continue this work, and we're certainly going to be looking at those questions.

Dr Ramon Berguer (Detroit, Mich). My congratulations for your excellent presentation. I just have curiosity about an intriguing group you mentioned in your factors of risk analysis: the patients that were operated on without systemic heparinization. I can't quite understand. How many of those patients were in the series, and do you have any idea how relevant this was to the incidence of reported stroke?

Dr Kresowik. Yes, it's a very small number. I think the overall number was 98.6% who were operated on using heparin, which is why I didn't focus on heparin use as a process with a lot of room for improvement. Even with the small numbers of patients who did not receive heparin, there was a significant difference in outcome. The risk reduction with the use of heparin was 50%.

Dr Robert W. Hobson II (Newark, NJ). Excuse me for extending the discussion, but I can't believe this audience hasn't responded to your comments about the combined CABG and endarterectomy cases with an over 17% 30-day stroke and death rate. Did your analysis give you any insight as to the etiology of the strokes occurring in that group? Do you have any insight as to who did the procedures, what their technical competency was, and why in the world the rate was so extraordinarily high?

Dr Kresowik. I am unable to provide more insight. Again this is the subgroup consisting of a sample from 10 states. There were 236 patients who underwent the combined procedure, so it's not a small number. But it's a small number from each state, and we didn't analyze it by surgeon. Only 12% of that group actually had indications of TIA or stroke, so the vast majority of patients were asymptomatic or had only nonspecific symptoms preoperatively, which is really disconcerting in terms of the actual morbidity that we found.